

### **Remarks/Arguments**

Applicants have received and carefully reviewed the Office Action of the Examiner mailed September 17, 2008. Currently, claims 1-9, 15, 21, 22, 24-38, and 51-65 remain pending. Claims 1-9, 15, 21, 22, 24-38, and 51-65 have been rejected. In this amendment, claims 62-65 have been amended. Favorable consideration of the following remarks is respectfully requested.

#### ***Claim Objections***

In paragraph 2 of the Office Action, claims 63-65 were objected to as improperly depending from claims 51 and 52. With this Amendment, Applicant has amended claim 63 to depend from claim 62, claim 64 to depend from claim 63, and claim 65 to depend from claim 62. Withdrawal of the rejection is respectfully requested.

#### ***Claim Rejections – 35 USC § 102***

In paragraph 4 of the Office Action, claims 62-64 were rejected under 35 U.S.C. 102(b) as being anticipated by Cox (U.S. Patent No. 5,257,974). After careful review, Applicant must respectfully traverse this rejection.

Turning to claim 62, which recites:

62. (Currently Amended) A catheter assembly comprising:  
a catheter shaft;  
an unexpanded balloon, the unexpanded balloon arranged on the catheter shaft and having at least a first tapered end; and  
a rotatable sheath, the rotatable sheath rotatably disposed about at least a portion of the unexpanded balloon, the rotatable sheath including a first radially tapered end that is arranged in radial alignment with the first tapered end of the unexpanded balloon, the first radially tapered end of the rotatable sheath being configured to complement the first tapered end of the unexpanded balloon.

Nowhere does Cox appear to teach or suggest “the first radially tapered end of the rotatable sheath being configured to complement the first tapered end of the unexpanded balloon”, as recited in claim 62.

Instead, with reference to Figures 31A and 32, Cox appears to teach a compliancy adaptor 458 including a sleeve 460 and a positioning member 462. Sleeve 460 is generally tubular-shaped, with outer surface 464, inner surface 466 and central opening 468. Central opening 468 permits sleeve 460 to be positioned over a shaft of a dilation balloon catheter. (See

column 16, lines 52-66). A first side 476 of the sleeve has a length greater than a second side 478, such that the distal end 470 and the proximal end 478 are angled from first side 476 to second side 478. (See column 17, lines 6-13). Nothing in Cox appears to teach or suggest the sleeve 460 including a first radially tapered end being configured to complement the first tapered end of the unexpanded balloon. In fact, nowhere in the Office Action does the Examiner appear to address the limitation “the rotatable sheath being configured to complement the first tapered end of the unexpanded balloon”. Applicant respectfully asserts that the angled proximal and distal ends of the sleeve taught by Cox does not complement the taper of the balloon. Thus, Cox does not appear to teach or suggest “the first radially tapered end of the rotatable sheath being configured to complement the first tapered end of the unexpanded balloon”, as recited in claim 62.

As the Examiner is aware, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As such, Cox appears to fail to teach each and every element of claim 62. Furthermore, there appears to be no reason to modify the teachings of Cox to arrive at the claimed invention. Therefore, for at least these reasons, claim 62 is believed to be patentable over Cox. For similar reasons and others, claims 63-64, which depend from claim 62 and include additional limitations, are believed to be patentable over Cox.

### ***Claim Rejections – 35 USC § 103***

In paragraph 6 of the Office Action, claims 1, 2, 5-9, and 31-38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (U.S. Patent No. 5,257,974). After careful review, Applicant must respectfully traverse this rejection.

1. (Previously Presented) A catheter assembly comprising:  
a catheter, the catheter comprising a catheter shaft and an unexpanded balloon positioned at a distal end portion of the catheter shaft, the unexpanded balloon including a first portion having a first outer diameter and a second portion having a second outer diameter that is different than the first outer diameter; and  
a rotatable sheath, the rotatable sheath rotatably disposed about at least a portion of the unexpanded balloon, the rotatable sheath including a first portion having a first portion inner diameter and a second portion having a second portion inner diameter that is different than the first portion inner diameter, the first portion of the rotatable sheath being arranged axially adjacent the second portion

of the rotatable sheath, the first portion of the rotatable sheath arranged in radial alignment with the first portion of the unexpanded balloon and the second portion of the rotatable sheath arranged in radial alignment with the second portion of the unexpanded balloon.

Nowhere does Cox appear to teach or suggest at least “the rotatable sheath including a first portion having a first portion inner diameter and a second portion having a second portion inner diameter that is different than the first portion inner diameter, the first portion of the rotatable sheath being arranged axially adjacent the second portion of the rotatable sheath, the first portion of the rotatable sheath arranged in radial alignment with the first portion of the unexpanded balloon and the second portion of the rotatable sheath arranged in radial alignment with the second portion of the unexpanded balloon”, as recited in claim 1.

In the Office Action, the Examiner cites to Figure 22 of Cox as teaching the rotatable sheath and to Figure 8 of Cox as teaching tapered ends. Applicant respectfully asserts that nothing in these two embodiments appear to teach or suggest a rotatable sheath disposed about at least a portion of an unexpanded balloon and having the claimed first and second inner diameters. Figure 22 appears to teach a perfusion adaptor including a ductal sleeve 350 and a positioning member 352. (See column 14, lines 8-9). The ductal sleeve 350 can be positioned over balloon 378 so that ducts 368 lie between balloon 378 and wall 380 of artery 382. Ribs 366 provide sufficient structural support to help keep ducts 368 open. (See column 14, lines 36-45). Nothing in the embodiment of Figure 8 appears to teach or suggest the claimed first and second inner diameters.

Figure 8 appears to teach a perfusion adaptor 140, which includes hollow member 142 and positioning member 143. (See column 9, lines 20-23). The perfusion adaptor 140, similar to perfusion adaptor 30 of Figure 2, is configured so that the hollow member 142 is positioned between a balloon and the artery wall to permit a flow of blood past the balloon. (See column 6, lines 44-47). Perfusion adapter 142 includes a tapered distal region 144. (See column 9, lines 25-26). As can be seen, nothing in the embodiment of Figure 8 appears to teach or suggest that the perfusion adaptor 140 can be disposed about a balloon, but instead, Cox appears to teach the perfusion adaptor 140 positioned between the balloon and the artery wall. (See, for example, Figure 2A and 2B). As such, nowhere does Cox appear to teach or suggest a rotatable sheath disposed about at least a portion of an unexpanded balloon and having the claimed first and second inner diameters, as in claim 1. Therefore, for at least these reasons, claim 1 is believed to

be patentable over Cox. For similar reasons and others, claims 2, 5-9, and 31-38, which depend from claim 1 and include additional limitations, are believed to be patentable over Cox.

Turning to claim 2, which recites:

2. (Original) The catheter assembly of claim 1 further comprising a guidewire housing, the guidewire housing defining a guidewire lumen for passage of a guidewire therethrough, at least a portion of the guidewire housing being engaged to at least a proximal portion of the rotatable sheath.

Nothing in Cox appears to teach or suggest at least “a guidewire housing, the guidewire housing defining a guidewire lumen for passage of a guidewire therethrough, at least a portion of the guidewire housing being engaged to at least a proximal portion of the rotatable sheath”, as recited in claim 2. Further, nowhere in the Office Action does the Examiner cite any portion of Cox as teaching or suggesting the claimed guidewire housing. Therefore for at least these reasons, claim 2 is believed to be patentable over Cox. Applicant respectfully requests that if the Examiner is to maintain the rejection of claim 2 over Cox, that the Examiner point out where Cox teaches or suggests all the limitations of claim 2.

In paragraph 8 of the Office Action, claims 3, 4, 15, 21, 22, and 65 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (U.S. Patent No. 5,257,974) in view of Wilson et al. (U.S. Patent No. 6,165,195). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claims 1 and 62 are believed to be patentable over Cox and nothing in Wilson et al. appears to remedy the noted shortcomings. Therefore, claims 3, 4, 15, 21, 22, and 65, which depend from claim 1 or claim 62 and include additional limitations, are believed to be patentable over Cox and Wilson et al.

In paragraph 9 of the Office Action, claims 24-29 and 51-61 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (U.S. Patent No. 5,257,974) in view of Wilson et al. (U.S. Patent No. 6,165,195), and further in view of Healy et al. (U.S. Patent No. 5,670,161). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 1 is believed to be patentable over Cox and Wilson et al. Nothing in Healy et al. appears to remedy the noted shortcomings of Cox and Wilson et al. Therefore, for at least these reasons, claims 24-29 and 51-61, which depend from claim 1 and include additional limitations, are believed to be patentable over the combination of Cox, Wilson et al., and Healy et al.

In paragraph 10 of the Office Action, claim 30 was rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (U.S. Patent No. 5,257,974) in view of Lenker et al. (U.S. Patent

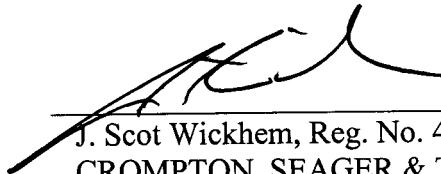
No. 6,350,278). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 1 is believed to be patentable over Cox and nothing in Lenker et al. appears to remedy the noted shortcomings of Cox. Therefore, for at least these reasons, claim 30, which depends from claim 1 and includes additional limitations, is believed to be patentable over the combination of Cox and Lenker et al.

### ***Conclusion***

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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